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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/779,412	02/13/2004	Guillermo C. Bazan	RUC 86053 UT	7769

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EXAMINER	
SISSON, BRADLEY L	

ART UNIT	PAPER NUMBER
1634	

MAIL DATE	DELIVERY MODE
09/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/779,412	BAZAN ET AL.	
	Examiner	Art Unit	
	Bradley L. Sisson	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10,12-24 and 27-33* is/are pending in the application.

4a) Of the above claim(s) *3-5,7,8,10,16,19,20,23,24 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,6,9,12-15,17,18,21,22,27,28 and 30-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07 February 2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Upon further consideration of applicant's remarks found at page 9 of the response of 08 July 2008, claim 33 is hereby rejoined.

2. Claims 3-5, 7, 8, 10, 16, 19, 20, 23, 24, and 29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 September 2006.

3. This application contains claims 3-5, 7, 8, 10, 16, 19, 20, 23, 24, and 29 drawn to an invention nonelected with traverse in the reply filed on 18 September 2006. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Drawings

4. Acknowledgement is made of applicant's indication of the Office's prior granting of a petition to accept colored drawings in the Office letter of 09 August 2006.

5. A review of the file contents finds that the restriction requirement has mailed on 09 August 2006. The petition of 13 February 2004 was granted in the letter of 11 August 2006. Accordingly, the objection to the drawings is hereby withdrawn.

Specification

6. The specification has been found to contain numerous trademarks. See, for example, pages 18, 24, and 25 of the specification. At page 10 of the response of 08 July 2008 applicant states "Applicant have by amendment above inserted the appropriate trademark symbol, each of which is accompanied by the appropriate generic language."

7. As set forth in the prior Office action, and a repeated herein, the trademarks are to be capitalized wherever they appear and be accompanied by their respective generic terminology. While applicant has asserted that the trademarks are now accompanied by the appropriate generic language, no such amendment has been found. Accordingly, the objection is maintained.

8. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 1, 2, 6, 9, 12-15, 17-18, 21,22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Said claims are indefinite with respect to just what constitutes the metes and bounds of "polynucleotide binding protein." A review of the disclosure finds a definition at page 23, lines

15-20, however, said definition is non-limiting. Accordingly, the metes and bounds of the claims cannot be readily determined.

12. Claims 1, 2, 6, 9, 12-15, 17-18, 21,22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite as it is not readily apparent just what the claimed method is to result in. Accordingly, one is not able to ascertain if the recited steps result in the intended product and/or whether all essential method steps are recited. As presently worded, the claimed "assay" is to result in detecting light, no correlation is required to be drawn from said detection.

Response to argument

13. At page 10 of the response applicant asserts that the above rejection of claims "is not a legal ground of rejection." Argument is also presented that "this term contains only three words, each of which is known in the art, the term is clear and definite to the person of skill."

14. The above argument ahs been fully considered and has not been found persuasive. The number of words that the expression comprises has no bearing on the definiteness of the term. Further, that each word may have a separate meaning does not define what the expression is to be interpreted as being limited. To the degree that applicant's representative asserts what one of ski in the art would have interpreted the term to mean is not dispositive. Attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of

> attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

15. Acknowledgement is made of applicant's representative directing attention to page 22 of the disclosure as providing guidance as to how the term could be interpreted. This page has been considered and has not been found persuasive. It is noted that page 23 states:

> The PBPs can be naturally occurring proteins, mutants of naturally occurring proteins, randomly produced proteins produced, for example, by molecular evolution methods, or suspected polynucleotide binding proteins of unknown binding specificity.

16. As set forth in this passage, a polynucleotide binding protein (PBP) can be seemingly any protein under the sun that can bind a polynucleotide, be it directly or indirectly, and also includes those proteins "of unknown binding specificity." Given the innumerable potential embodiments, it is not readily apparent what is and what is not encompassed by this term. Accordingly, the rejection is maintained.

17. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

18. Claims 1, 2, 6, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

19. As set forth in *Enzo Biochem Inc., v. Calgene, Inc.* (CAFC, 1999) 52 USPQ2d at 1135, bridging to 1136:

> To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *Genentech, Inc. v. Novo Nordisk, A/S*, 108 F.3d 1361, 1365, 42 USPQ2d 1001, 1004 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)). Whether claims are sufficiently enabled by a disclosure in a specification is determined as of the date that the patent application was first filed, see *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).... We have held that a patent specification complies with the statute even if a "reasonable" amount of routine experimentation is required in order to practice a claimed invention, but that such experimentation must not be "undue." See, *e.g.*, *Wands*, 858 F.2d at 736-37, 8 USPQ2d at 1404 ("Enablement is not precluded by the necessity for some experimentation . . . However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' ") (footnotes, citations, and internal quotation marks omitted). In *In re Wands*, we set forth a number of factors which a court may consider in determining whether a disclosure would require undue experimentation. These factors were set forth as follows: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. *Id.* at 737, 8 USPQ2d at 1404. We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts.").

<u>The quantity of experimentation necessary,</u>

The quantity of experimentation needed is vast, on the order of several man-years, with little if any reasonable expectation of success.

<u>The amount of direction or guidance presented,</u>

The amount of guidance provided is extremely limited, leaving the fundamental issues of full enablement to the pubic to resolve.

The presence or absence of working examples,

Pages 29-32 of the specification have been found to provide seven examples. Of these seven examples, none have been found to set forth specific reaction conditions whereby any target RNA can be detected. The examples do suggest that a Tat-C probe as well as a SH3-C peptide can bind to a target sequence. The specification, however, does not set forth reproducible conditions under which the polynucleotide binding protein is synthesized and used. Further, the specification does not set forth reproducible conditions under which the elected fluorescent dye is produced and used in combination with the elected species of nucleic acid- single stranded RNA.

Acknowledgement is made of Example 4, and that RNA is bound by Tat-C* probe. It is further noted that specification at page 29 states:

> The polypeptides modified by fluorescein on the N- terminus (Tat-C* and SH3-C*) were custom-made by Sigma-Genosys (Texas, USA).

A review of the specification fails to identify how these "custom-made" probes were in fact prepared. Further, a review of the specification fails to show that these "custom-made" probes were commercially available at the time of filing. Absent such essential starting materials, one is left to conduct routine, trial-and-error experimentation for the development of even a single probe, much less probes that would allow for the binding of any RNA of interest.

The specification also teaches that TAR RNA was secured through a commercial source. The specification does not teach that the RNA oligonucleotide has any specific, credible, and substantial utility.

The nature of the invention & the predictability or of the art

The claimed method relates to the detection of nucleic acids through the use of non-specific binding members where a fluorescent signal is to be detected. As noted above, the method employs non-specific binding of nucleic acids. At best, the method would be able to allow for the detection of nucleic acids in general, yet there is no limitation that ties the binding of the polynucleotide binding protein to any level of specificity. It is not enough that the claimed method result in some product. In order to satisfy the requirement of enablement, it is imperative that the claimed method result in a product that satisfies the utility requirement under 35 USC 101, and do so in a predictable manner and that said method be disclosed in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains. The claimed method is not so limited.

The claimed method requires one to use a "polynucleotide binding protein." As noted above, the tern has been deemed to be indefinite. The specification has not been found to set forth any example, real or prophetic, or any other description whereby any specific polynucleotide binding protein will result in the identification of useful RNA in a predictable manner. As noted in *In re Fisher* 166 USPQ 18 (CCPA, 1970):

> In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

The breadth of the claims.

The claims fairly encompass the detection of any and all manner of nucleic acids. While applicant has elected the species of single stranded RNA, there is nothing that would preclude

the same binding and signaling moieties from binding non-target molecules, and thereby result in false positive signals. Further, the specification is silent as to how a skilled artisan would differentiate between signals that arose from a non-target as well as target nucleic acids.

20. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 6, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Response to argument

21. At page 12 of the response 9 of 08 July 2008, hereinafter the response, applicant's representative directs attention to page 24 of the disclosure, and states further: "Not only do those of skill in the art understand how to N-label peptides with fluorescein, a publication for doing so was cited in the specification."

22. It is noted that the cited document is not a published patent or published patent application. Accordingly, material essential to the enablement cannot be simply referenced, but need to be specifically brought in to the instant disclosure.

23. It is further noted that the claimed invention is not limited to the use of any one or combination of proteins, but encompass mutants, and proteins that have an unknown binding potential (supra). It is noted that page 23 states:

> The PBPs can be naturally occurring proteins, mutants of naturally occurring proteins, randomly produced proteins produced, for example, by molecular evolution methods, or suspected polynucleotide binding proteins of unknown binding specificity.

24. As set forth in this passage, a polynucleotide binding protein (PBP) can be seemingly any protein under the sun that can bind a polynucleotide, be it directly or indirectly, and also includes those proteins "of unknown binding specificity."

Neither the specification nor applicant's remarks set forth the materials and reaction conditions necessary to make and use the components encompassed by the claimed method. While argument has been made that the protein used in the example was obtained commercially, closer inspection of the facts suggests otherwise. In support of this position, attention is directed to specification at page 29, which states:

> The polypeptides modified by fluorescein on the N- terminus (Tat-C* and SH3-C*) were custom-made by Sigma-Genosys (Texas, USA).

25. A review of the specification fails to identify how these "custom-made" probes were in fact prepared.

26. At page 12 of the response applicant's representative asserts:

> The working examples provide specific techniques for detecting a viral component of a virus currently plaguing humankind. Detection of that viral component in a sample is of immediate apparent utility to those of skill in the art, as well as to the general public.

27. The above argument has been considered and has not been found persuasive, as the claims are not so limited. "Claims are to be given their broadest reasonable interpretation that is consistent with the specification. 'That claims are interpreted in light of the specification does not mean that everything in the specification must be read into the claims.' *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957, 220 USPQ 592, 597 (Fed. Cir. 1983), cert. denied, 469 U.S. 835 (1984 (MPEP 2164.08)

28. At page 12, bridging to page 13, of the response applicant's representative again asserts that all of the *Wands* factors are to be addressed in the body of the rejection.

29. This argument has not been found persuasive for as set forth in the citation of *Enzo*, and is reproduced below in part:

> We have also noted that all of the factors need not be reviewed when determining whether a disclosure is enabling. See *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (noting that the *Wands* factors "are illustrative, not mandatory. What is relevant depends on the facts."

30. It is further noted that the above rejection addresses the following factors:

a. The quantity of experimentation necessary,

b. The amount of direction or guidance presented,

c. The presence or absence of working examples,

d. The nature of the invention

e. The predictability or of the art; and

f. The breadth of the claims.

The factors not specifically addressed are: the state of the prior art, and the relative skill of those in the art. At page 13 of the response applicant's representative asserts that "the ignored factors strongly favor the Applicants" and "must be analyzed." This argument has been considered and has not been found persuasive. A review of the remarks and of the application as originally filed, fails to find where applicant has asserted, by way of evidence, how the level of skill and state of prior art, alone or in combination with the other factors, is sufficient to fully enable the claimed invention.

31. Acknowledgement is made of applicant's representative providing copies of web pages of products as well as an article. It is noted with particularity that the web pages were visited on

07 July 2008. As for the article, it has not been found to contain any information regarding when it was published, or where it was published.

32. The instant application was filed on 13 February 2004 and claims benefit of priority to provisional application filed 13 February 2003. Accordingly, documents visited and printed from the internet on 07 July 2008 do not demonstrate what was known in the art as of the effective filing date. It is further noted that such showings do not take the place of sworn (declarations/affidavits) evidence and from which assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 USC 1001. *Ex parte Gray* 10 USPQ2d 1922 at 1928 (BPAI 1989). Accordingly, applicant's representative's argument is non-persuasive.

33. To the extent that applicant's representative has made assertions as to what the level of skill is, and/or what one of skill in the art would be capable of doing, attention is directed to MPEP 2145.

> Attorney argument is not evidence unless it is an admission, in which case, an examiner may use the admission in making a rejection. See MPEP § 2129 and § 2144.03 for a discussion of admissions as prior art.
> The arguments of counsel cannot take the place of evidence in the record. *In re Schulze*, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965); In re Geisler, 116 F.3d 1465, 43 USPQ2d 1362 (Fed. Cir. 1997) ("An assertion of what seems to follow from common experience is just attorney argument and not the kind of factual evidence that is required to rebut a prima facie case of obviousness."). See MPEP § 716.01(c) for examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration.

34. For the above reasons, and in the absence of convincing evidence to the contrary, claims 1, 2, 6, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement.

Claim Rejections - 35 USC § 101 & 112

35. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

36. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

37. Claims 1, 2, 6, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility. Attention is directed to MPEP 2107.01 I [R-5], which states in part:

> A. Specific Utility
>
> A "specific utility" is specific to the subject matter claimed >and can "provide a well-defined and particular benefit to the public." *In re Fisher*, 421 F.3d 1365, 1371, 76 USPQ2d 1225, 1230 (Fed. Cir. 2005)<. ..For example, indicating that a compound may be useful in treating unspecified disorders, or that the compound has "useful biological" properties, would not be sufficient to define a specific utility for the compound. >See, e.g., *In re Kirk*, 376 F.2d 936, 153 USPQ 48 (CCPA 1967); *In re Joly*, 376 F.2d 906, 153 USPQ 45 (CCPA 1967).< Similarly, a claim to a polynucleotide whose use is disclosed simply as a "gene probe" or "chromosome marker" would not be considered to be specific in the absence of a disclosure of a specific DNA target. >See *In re Fisher*, 421 F.3d at 1374, 76 USPQ2d at 1232 ("Any EST [expressed sequence tag] transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses.... Nothing about [applicant's] seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the [ ] application or indeed from any EST derived from any organism. Accordingly, we conclude that [applicant] has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.").< A general statement of diagnostic utility, such as diagnosing an unspecified disease, would ordinarily be insufficient absent a disclosure of what condition can be diagnosed. Contrast the situation where an applicant discloses a specific biological activity and reasonably correlates that activity to a disease condition. Assertions falling within the latter category are sufficient to identify a specific utility for the invention. Assertions that fall in the former category

> are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a "useful" invention may arise from what has been disclosed by the applicant. *Knapp v. Anderson*, 477 F.2d 588, 177 USPQ 688 (CCPA 1973).
>
> B. Substantial Utility
>
> *> "[A]n application must show that an invention is useful to the public as disclosed in its current form, not that it may prove useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Fisher*, 421 F.3d at 1371, 76 USPQ2d at 1230. The claims at issue in Fisher were directed to expressed sequence tags (ESTs), which are short nucleotide sequences that can be used to discover what genes and downstream proteins are expressed in a cell. The court held that "the claimed ESTs can be used only to gain further information about the underlying genes and the proteins encoded for by those genes. The claimed ESTs themselves are not an end of [applicant's] research effort, but only tools to be used along the way in the search for a practical utility.... [Applicant] does not identify the function for the underlying protein-encoding genes. Absent such identification, we hold that the claimed ESTs have not been researched and understood to the point of providing an immediate, well-defined, real world benefit to the public meriting the grant of a patent." *Id*. at 1376, 76 USPQ2d at 1233-34).

38. The method of said claims is to result in the detection of light emitted by fluorescein (a signaling chromophore). The method is note required to have any level of specificity, or that the target single-stranded RNA has any specific, substantial, and credible utility. Indeed, the claimed method fairly encompasses the binding of mRNA associated with expressed sequence tags, and for which no known utility exists, assuming *arguendo*, that the polynucleotide binding protein does have specificity for a given RNA molecule.

39. The claims do not distinguish between those nucleic acids that do and do not have utility under 35 USC 101 but rather, encompasses any and all manner of nucleic acids.

40. While the claims currently before the Office are all drawn to a method and not to a product, such does not alter the requirements of satisfying the utility requirements of 35 USC

101. In support of this position, attention is directed to *Brenner, Comr. Pats. v. Manso*n, 148 USPQ 689 (US Sup Ct 1966):

> We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. 24 That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself.
> This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of the invention of something "useful," or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.

41. Applicant is urged to consider amending the claims such that the claims are drawn to a method that results in a product that unquestionably does have utility under 35 USC 101 and which is adequately supported by the original disclosure.

42. Claims 1, 2, 6, 9, 12-15, 17, 18, 21, 22, 27, 28, and 30-33 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to argument

43. At page 13, bridging to page 14, of the response, applicant asserts that the claimed method does have utility under 35 USC 101. In support of this position, applicant's representative asserts that the invention could be used in detecting and/or quantitating nucleic acids. This argument has not been found persuasive as not all nucleic acids have utility. An example of nucleic acids that lack utility is expressed sequence tags. The present method does

not distinguish between nucleic acids generally and those that have utility. Accordingly, the general detection and/or quantification of nucleic acids is deemed to not qualify as a substantial utility.

44. For the above reasons and in the absence of convincing evidence to the contrary, the rejection is maintained.

Conclusion

45. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

46. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

47. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

48. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/
Primary Examiner, Art Unit 1634